

**MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG****Coartem<sup>®</sup> receives FDA approval becoming first artemisinin-based combination treatment (ACT) for malaria in the US**

- *Coartem is highly effective, well tolerated 3-day treatment with cure rates of over 96%*
- *More than 235 million Coartem treatments already supplied by Novartis for public sector use in Africa, helping save an estimated 600,000 lives*

**Basel, April 8, 2009** —Coartem<sup>®</sup> (artemether 20 mg/lumefantrine 120 mg), the leading artemisinin-based combination treatment (ACT) for malaria worldwide, has been approved by the US Food and Drug Administration (FDA).

Coartem is a fixed-dose combination of two novel antimalarials. It is a highly-effective three-day malaria treatment with cure rates of over 96%\* even in areas of multi-drug resistance<sup>1,2</sup>.

Each year millions of Americans travel to malaria-endemic regions on business or pleasure, and this has led to a rise in cases of ‘travelers malaria’<sup>3</sup>. Unlike patients in more than 80 countries, including in many European nations, US patients have not had access to ACTs like Coartem.

“Around the world, Coartem has eliminated suffering for millions and saved lives for hundreds of thousands of malaria patients,” said Dr. Daniel Vasella, Chairman and CEO of Novartis. “With a growing number of malaria cases in the US due to rising travel, it is important to make ACT treatment such as Coartem, the most effective therapy for malaria, available to American patients as well.”

Each year there are nearly one million malaria-related deaths around the world. In Africa alone, a child dies every 30 seconds from malaria<sup>4</sup>. To help alleviate the tremendous problem of access to treatment, Novartis provides Coartem treatments for public sector use in Africa without profit. To date, Novartis has provided more than 235 million Coartem treatments, which have helped save an estimated 600,000 lives - mostly children.

“Fighting malaria is very much in America’s interest and ACTs such as Coartem are important weapons against this infectious disease,” said Rear Admiral Tim Ziemer, US Malaria Coordinator. “We welcome FDA approval of Coartem.”

In the US, Coartem will be made available through pharmacies and hospitals.

Coartem is indicated for the treatment of acute uncomplicated infections due to *plasmodium falciparum*, the most dangerous form of malaria.

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\* Cure rates are PCR-corrected in the mITT population. For full details see reference.

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## **About Novartis**

Novartis AG provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, preventive vaccines, diagnostic tools, cost-saving generic pharmaceuticals and consumer health products. Novartis is the only company with leading positions in these areas. In 2008, the Group's continuing operations achieved net sales of USD 41.5 billion and net income of USD 8.2 billion. Approximately USD 7.2 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 96,700 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit <http://www.novartis.com>.

## **References**

- 1 Hatz C. et al. Treatment of acute uncomplicated falciparum malaria with arthemeter-lumefantrine in non immune populations: a safety, efficacy and pharmacokinetic study. Am.J.Trop.Med.Hyg. 2008
- 2 Abdulla S. et al. Efficacy and safety of arthemeter-lumefantrine dispersible tablets compared with crushed commercial tablets in African infants and children with uncomplicated malaria: a randomised, single blind, multicentre trial. Lancet . Published on line.
- 3 Malaria Surveillance Report, Centers for Disease Control and Prevention,; June 20, 2008 / 57(SS05);24-39, [http://www.cdc.gov/mmwr/preview/mmwrhtml/ss5705a2.htm?s\\_cid=ss5705a2\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/ss5705a2.htm?s_cid=ss5705a2_e)
- 4 Children and Malaria. World Health Organization Roll Back Malaria Web site. Available at : [http://www.rbm.who.int/cmuc\\_upload/0/000/015/367/RBMInfosheet\\_6.pdf](http://www.rbm.who.int/cmuc_upload/0/000/015/367/RBMInfosheet_6.pdf).
- 5 Malaria Fact Sheet. World Health Organization Web site. Available at : <http://www.who.int/mediacentre/factsheet/fs094/en/>.

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